PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	**Scott Schewe and Victor Schoenle and Jan Weber**
Application No.:	**10/617428**
Filed:	**July 10, 2003**
For:	**MEDICAL DEVICE TUBING WITH DISCRETE ORIENTATION REGIONS**
Examiner:	**Jeffrey Michael Wollschlager**
Group Art Unit:	**1732**

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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Docket No.: S63.2B-10941-US01

BRIEF ON APPEAL

This is a Brief on Appeal for the above-identified application in which Claims 23-25 and 43-45 are being appealed.

A Notice of Appeal was filed in this case on July 10, 2007. The fees required under §1.17(c) for filing this brief were addressed in the Notice of Appeal. The Commissioner is authorized to charge Deposit Account 22-0350 for any other fees which may be due with this appeal.

(i) Real party in interest.

The application is assigned to Boston Scientific Scimed, Inc., formerly known as Scimed Life Systems, Inc., One SciMed Place, Maple Grove, MN 55311-1566, a Minnesota Corporation and a subsidiary of Boston Scientific Corporation, One Boston Scientific Place, Natick, Massachusetts, 01760-1537, a Delaware Corporation

(ii) Related appeals and interferences.

There are no related appeals or interferences.

(iii) Status of claims.

Claims 1-45 have been filed. Claims 1-9 and 38-42 have been cancelled. Claims 10-37 and 43-45 are pending. Claims 10-22 and 26-37 have been allowed. Claims 23-25 and 43-45 have been rejected.

Claims 23-25 and 43-45 are being appealed.

(iv) Status of amendments.

An amendment was filed on Jan 19, 2007 and was not entered.

An amendment was filed April 3, 2007 and has been entered.

(v) Summary of claimed subject matter.

Independent claim 23, recites a method of making a parison for forming a medical device balloon [original claim 23; 3:16-23; 5:10:-15; (30) Fig. 2 and (50) Fig. 3] in which portions of the parison are slated to form cone [(34)(38); (54)(58)] and waist [(32) (40); (52) (60)] portions of the balloon and a portion is slated to form the balloon body [original claim 23; (36);(56); 6:31-

7:11; 7:28-8:4], the method comprising a step of extruding polymeric material to form a tube, and forming the parison having said slated portions from the tube, wherein the extruding step is controlled to provide the extruded tube with a varying longitudinal orientation, such that the slated parison formed therefrom has a lower or higher orientation for the cone and waist slated portions of the parison relative to the portion slated to form the balloon body [original claim 23; 3:19-21; 4:23-5:5; 6:7-20; 8:13-9:18; 11:28-12:7].

Independent claim 43 recites a method of forming a polymeric tubing segment for a medical device comprising extruding a tube of polymeric material through a die and cooling the extruded tubing by drawing it through a cooling region spaced at a gap length from the die to the cooling bath, wherein the drawing rate, or the gap length, or the cooling rate of the cooling region, or any combination thereof, is altered along the length of the segment, whereby the segment is formed with at least two regions along the length thereof, a first of said regions and a second of said regions having different elongation at yield properties relative to each other [original claim 26, 4:23-28; 7:23-27; 8:13-9:18] and wherein

said alteration of the drawing rate, or the gap length, or the cooling rate of the cooling region, or combination thereof, is selected on the basis of the elongation at yield properties of said first and second regions [original claim 26, 4:23-28; 8:13-9:18].

(vi) Grounds of rejection to be reviewed on appeal.

A) Review on Appeal of the Examiner's contention that claims 23-25 are anticipated by Pepin et al, US 5,614,136 viewed in light of Chen et al US 6,905,743.

B) Review on Appeal of the Examiner's contention that claims 43-45 are anticipated by Pepin et al, US 5,614,136 viewed in light of Chen et al US 6,905,743.

(vii) Argument.

(A) The Examiner erred in rejecting claims 23-25 as anticipated by Pepin et al, US 5,614,136 viewed in light of Chen et al US 6,905,743.

Claims 23-25 stand rejected under 35 USC §102(b) as being anticipated by Pepin et al (US 5,614,136) when taken with Chen et al (US 6,905,743).

(1) Applicable Law

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California,* 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). The identical invention must be shown in as complete detail as is contained in the ... claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). "[T]o constitute an anticipation, all material elements recited in a claim must be found in one unit of prior art." *In re Marshall* , 578 F.2d 301, 304, 198 USPQ 344, 346 (CCPA 1978); *Ex parte Gould* 6 USPQ2d 1680 (BdPatApp&Int 1987). *See also,* MPEP 2131. Reliance on inherency in an anticipation analysis requires evidence that the missing descriptive matter is "necessarily present" in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. MPEP §2131.01 (III); *Continental Can Co. USA v. Monsanto Co.*, 948 F.2d 1264, 1268, 20 USPQ2d 1746, 1749 (Fed. Cir. 1991). Inherency may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient. *Continental Can*, 948 F.2d at 1269, 20 USPQ.2d at 1749; *In re Robertson*, 49 USPQ2d 1949, 1951 (Fed. Cir. 1999).

(2) The Examiner's Rejection

Regarding claim 23 the Examiner asserts

> Pepin et al teaches the claimed process of forming a a [*sic.*] polymeric tube segment, comprising: extruding a polymeric tube (Fig. 6); drawing/pulling the tube through a cooling bath (Fig 6); and altering/varying the drawing rate to change the dimensions in at least two regions or predetermined locations along the tube (3:9-60; 6:5-25, and Fig. 7) Pepin et al. specifically teaches that the varying the speed of the pullet or drawing rate changes the volume of extruded material in a given length (6:5-24) which is essentially the rate of extrusion Pepin et al also teaches varying the pressure of the internal air/gas supply during processing to form different tubular segments (5:58-6:48)
>
> Pepin et al. does not specifically teach that different orientations (ie molecular orientation) occurs during drawing. Nonetheless, it is inherent that axial/longitudinal molecular orientation is proportional is the drawing/pulling rate. This is evidenced by Chen et al. which teaches that a high speed puller imparts a shearing force on a molten/deformable material thereby causing molecular orientation (5:20-45)
>
> (Final Action, 1/09/2007, pg. 3)

Regarding claims 24-25 the Examiner further asserts:

> Pepin et al. also teaches varying the drawing/pulling rate between at least two different value sets or profiles wherein the wall thickness varies including tapers or waist portions (Figs 7 exhibits a repeating pattern between two different diameters and Fig. 2a for wall thickness variations). It is submitted that the high pulling speeds which would cause higher thawing and smaller diameters (i.e. at a constant extrusion rate) would experience higher shearing forces and thereby inherently have a higher degree of molecular orientation in these regions relative to the larger diameter regions.
>
> (Final Action, 1/09/2007, pg. 3)

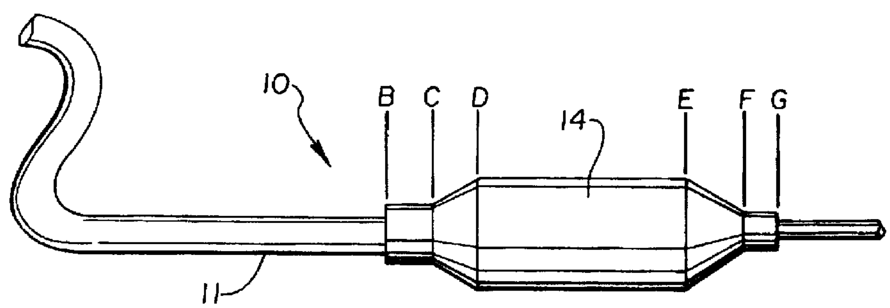
For purposes of this appeal applicant does not dispute the asserted inherency of different orientations occurring under at least some of the drawing rate changes. Accordingly, Chen et al will not be discussed in detail. Nevertheless, in formulating this rejection the Examiner has fundamentally erred by disregarding critical recitations in claim 23 which are not met, expressly or inherently, by Pepin et al.

(3) Arguments Applicable to Each of Claims 23-25

The Examiner's errors begin with the preamble of independent claim 23, which is representative for this argument. Claim 23 pertains to a method of forming a ***balloon parison,*** not a method of forming a "polymeric tube segment," as asserted by the Examiner.

To understand claim 23 a little background review is helpful. Medical device balloons used on catheters and similar devices typically have a body portion (the working portion of the balloon, usually but not always cylindrical), cone portions at either ends of the body portion where the diameter reduces and waist or cuff portions at the small ends of the cones which provide surface for a bonding to shaft portions of the catheter or other such device. An illustrative non-limiting example of such a balloon mounted on a catheter is shown in Fig. 1 of US 5,714,110, Wang et al, a patent incorporated by reference in the present application (2:11; 4:10-13):

Fig. 1



The balloon is indicated at 14. The balloon body portion extends between D and E, the cones between C and D, and between E and F, and the waists between B and C and between F and G.

A conventional way of forming such balloons is to radially expand ("blow") a tubular parison, usually into a mold, cone or sleeve form. See, *e.g.* Fig 1 of US 4,490,421, Levy; Fig. 3 of US 4,906,244, Pinchuck et al; Fig. 4 of US 5,270086, Hamlin; Fig. 3 of US 4,963,313, Noddin et al; Fig. 4 of US 5,714,110, Wang et al, all incorporated by reference in the present application (1:14; 1:23; 2:10-11; 4:10-13). A balloon parison starts out as an extruded tube, but at some point prior to actually blowing the balloon different regions are slated to become different parts of the balloon. This may occur by the act of cutting the tube to a particular size for mounting in a

particular blow molding apparatus, it may occur by intermediate processing of a tubing segment so that the tube has different dimensions, it may not occur until a tubing portion is advanced to a particular location of the mold apparatus. Regardless of how it gets to that point, once slating has occurred the tubing segment is a parison that is qualitatively differentiated from tubing extrusions intended for other purposes such as catheter shaft or tip sections. ***At least the slating assignment*** itself provides a characterizing difference from those other types of tubing.

Claim 23 pertains to a method of making parisons that have arrived at the point where they have slated portions with balloon cone, waist and body sections. The characteristic feature of the invention relates to a particular ***relationship*** between the extrusion step for forming the tubing and the slating of the tubing portions. In particular claim 23 recites a step of extruding polymeric material to form a tube, and "forming the parison having said slated portions from the tube, wherein the extruding step is controlled to provide the extruded tube with a varying longitudinal orientation, such that the slated parison formed therefrom has a lower or higher orientation for the cone and waist slated portions of the parison relative to the portion slated to form the balloon body."

Therefore, in order to satisfy the ***relationship*** recited in claim 23, tubing must not only be extruded with different longitudinal orientation at various points along the length, it must also be formed into a parison with the body portion slated so as to have a different orientation for the body slated portion compared to the cone and waist slated portions. The claim does not read merely on extruded tubing with different orientation along its length. If an extruded tubing segment is never formed into a parison, or if it is formed into a parison in which the slated portions for cone and waist do not have different extruded longitudinal orientation from the body slated portion, the process of claim 23 has not been met.

In formulating the rejection the Examiner has simply ignored these claim elements. Pepin et al does not show "each and every element as set forth in the claim," the fundamental requirement for any anticipation rejection.

Pepin et al describes a method of manufacturing a dimensionally variable catheter tubing (2:29-31). More specifically Pepin et al states,

> the present invention may be used to manufacture dimensionally variable tubular members for use in manufacturing catheter shafts, catheter tips, fuseless catheter systems, and other products where dimensionally varying characteristics are desirable.
>
> (3:31-35)

Pepin et al says nothing about forming balloons, or about forming balloon parisons, from the disclosed dimensionally variable tubing.

The Examiner implies that Pepin et al's Fig. 7 meets the slated recitations of claim 23. That figure is reproduced below:

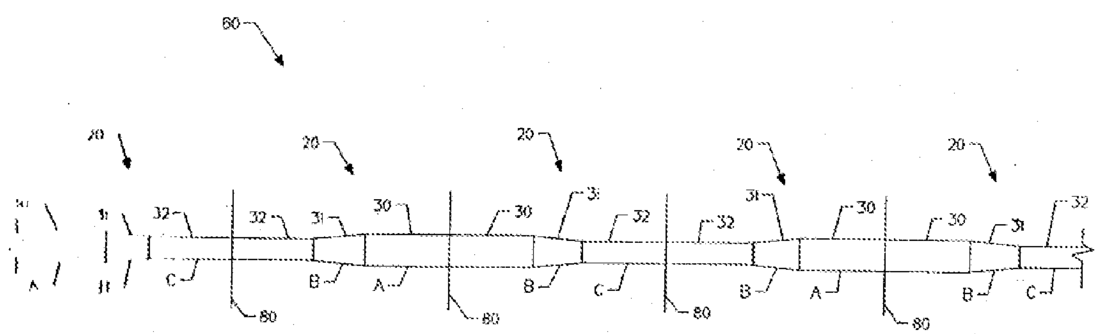


FIG. 7

Regarding this Figure Pepin states:

> In one preferred embodiment, controller 70 is programmed to provide a tubular member 60 having the dimensional characteristics shown in FIG. 7. Controller 70 controls pressurized air supply 46, extruder 42, and puller 50, to produce a tubular member having dimensionally varied sections A, B, and C. Section A is a larger dimensioned tubular member, which transitions through section B, to a smaller tubular member of section C. In one preferred embodiment, section A and C are three inches in length, and section B is less than one inch in length.

> Controller 70 times cutter 52 to efficiently cut at points 80, the continuous tubular member 60 into dimensionally precise ***soft catheter tips 20***. After passing tubular member 60 through cutter 52, each individual soft tip 20 includes a proximal section 30, a transitional section 31, and a distal section 32.
>
> (7: 43-52, emphasis added)

Thus it is clear that this Figure has nothing whatsoever to do with a balloon parison or a method of making a balloon parison. Moreover, while the respective sections 20 do have slated portions, the slating has nothing to do with balloons or balloon segments. These sections are slated as different regions of a catheter distal tip. Consequently they are unquestionably ***not*** slated as balloon waist, cone or body portions. There is no reasonable basis to assert that the tubing depicted in Figure 7 has been, or ever will be, slated in a way that satisfies the recitations of claim 23.

For the reasons given above claim 23, and claims 24-25 which depend therefrom, are clearly not anticipated by Pepin et al. Because Pepin et al does not show "each and every element as set forth" in claim 23 the Board is respectfully requested to reverse the anticipation rejection of claims 23-25.

(4) Additional Argument for Claim 24

Claim 24 depends from claim 23 and recites a more specific extrusion/slating relationship, namely: "the extruding step is controlled to provide the portion slated to form the body with a higher relative longitudinal orientation, the portions slated to form the waists of the balloon with a lower relative longitudinal orientation and the portions slated to form the cones of the balloon with a varying longitudinal orientation ranging between the higher and the lower relative orientations."

The Examiner's additional contentions regarding inherency of these claims are irrelevant since the slating relationship clearly cannot be inherently met by tubing not used to form balloon

parisons. In addition to the reasons given above, for the additional reason that Pepin et al fails to show this more specific extrusion/slating relationship, claim 24 is not anticipated by Pepin et al and the Board is requested to reverse the anticpation rejection of claim 24.

(B) The Examiner erred in rejecting claims 43-45 as anticipated by Pepin et al, US 5,614,136 viewed in light of Chen et al US 6,905,743.

Claims 43-45 also stand rejected under 35 USC 102(b) for anticipation by Pepin et al (US 5,614,136) when taken with Chen et al (US 6,905,743).

(1) Applicable Law

The legal requirements for anticipation are detailed in section (vii)(A)(1) above. "Each and every element as set forth in the claim must be present, expressly or inherently, in a single prior art reference.

(2) The Examiner's Rejection

The Examiner asserts regarding claim 43:

> Pepin et al. teaches the claimed process of forming a polymeric tube segment, comprising: extruding a polymeric tube (Fig 6); drawing/pulling the tube through a cooling bath (Fig. 6); and altering/varying the thawing rate to change the dimensions in at least two regions or predetermined locations along the tube (3:9-60; 6:5-25, and Fig. 7) Pepin et al also teaches varying the pressure of the internal air/gas supply during processing to form different tubular segments (5:58-6:48) Lastly, Pepin et al reaches that process is carried out to "meet required operation and performance characteristics" of the tubular member (7:15-25), which would be inherently inclusive of yield and break strengths (ie. elongation properties) of the final product.
>
> Pepin et al does not specifically teach that different orientations (ie molecular orientation) occurs during drawing. Nonetheless, it is inherent that axial/longitudinal molecular orientation is proportional is the drawing /pulling rate. This is evidenced by Chen et al which teaches that a high speed puller imparts a shearing force on a molten/deformable material thereby causing molecular orientation (5: 20-45).

(Final Action, 1/09/2007, pages 3-4)

Regarding claims 44 and 45 the Examiner states:

> Again, the examiner recognizes that all of the claimed effects and physical properties are not positively stated by the reference(s). However, the reference(s) teaches all of the claimed ingredients, process steps, and process conditions. Therefore, the claimed effects and physical properties would inherently be achieved by carrying out the disclosed process. If it is applicants' position that this would not be the case: (1) evidence would need to be presented to support applicants' position; and (2) it would be the examiner's position that the application contains inadequate disclosure that there is no teaching as to how to obtain the claimed properties and effects by carrying out only these process steps.
> (Final Action, 1/09/2007, page 4)

(3) Arguments Applicable to Each of Claims 43-45

Independent claim 43 is directed to a method of forming a polymeric tubing segment for a medical device. The method "comprises extruding a tube of polymeric material through a die and cooling the extruded tubing by drawing it through a cooling region spaced at a gap length from the die to the cooling bath, wherein the drawing rate, or the gap length, or the cooling rate of the cooling region, or any combination thereof, is altered along the length of the segment, whereby the segment is formed with at least two regions along the length thereof, a first of said regions and a second of said regions having different elongation at yield properties relative to each other and wherein

said alteration of the drawing rate, or the gap length, or the cooling rate of the cooling region, or combination thereof, ***is selected on the basis of the elongation at yield properties of said first and second regions.*** Claims 44 and 45 depend from claim 43 and so include all of its elements.

The applicant does not dispute that Pepin et al shows a process for extruding polymeric tubing for a medical device in which a drawing rate is altered to provide at least two regions along

the length thereof, a first of said regions and a second of said regions having different elongation at yield properties relative to each other.

Pepin et al however does not teach to ***select*** the alteration of the drawing rate on the basis of elongation at yield properties of the extrusion. Pepin seeks to change the dimension of the tubing and alters the drawing rate, or extrusion pressure on the basis of the tubing dimension produced. The tubing thickness dimension is easily measured. The relationship is direct. Nothing in Pepin teaches, suggests or motivates measurement of elongation at yield in selecting or in monitoring the extrusion process.

The claimed process requires that a process alteration "is selected on the basis of the elongation at yield properties of the first and second regions." Selecting "on the basis of" is a ***choice criterion*** for the process. Consequently, at some point, in the initial selection of extrusion parameters, in monitoring the extrusion, or both, a measurement of elongation at yield is determined and the result used to select an altered extrusion condition (*i.e.* drawing rate, gap length, cooling rate of the cooling region, or a combination thereof).

Since the "on the basis of" recitation defines a ***choice criterion***, consciousness greatly constricts the possibilities for inherency. Inherency cannot even arguably be satisfied without showing that there was a known relationship between some other parameter used as a selection criterion for altering the extrusion process and the elongation at yield of the resulting extrudate, and a desire to use the known parameter as a proxy for the elongation property. Neither Pepin et al nor Chen et al provide any evidence of such a relationship. Furthermore, Pepin's dimension measurement is not a proxy for anything. Pepin et al want to vary dimension, that is what they measure, and the process is altered accordingly.

Pepin et al clearly does not use elongation at yield, or a some other measurement as a

proxy for elongation at yield, as the basis for altering tubing extrusion condition. Therefore Pepin et al clearly does not expressly or inherently meet each and every element as set forth in the claim.

(4) Additional Arguments for Claims 44 and 45

Claims 44 and 45 depend from claim 43 and recite further recite:

> said alteration is selected to provide one of said regions with a elongation at yield which is at least 20% below the elongation at yield of another of said regions.
>
> (claim 44)

and

> said alteration is selected to provide one of said regions with a elongation at yield which is 30% below the elongation at yield of another of said regions.
>
> (claim 45)

Pepin et al nor Chen et al provide any teaching or suggestion that an elongation at yield of one region should be, respectively, at least 20%, or at least 30%, less than another region of the extruded tubing, much less that the extrusion should be altered to provide such a difference. "Each and every element as set forth in the claim" is not shown merely by chanting the word "inherently" as some sort of magical mantra.

There is no basis to assert that Pepin et al is using dimension or some other property measurement ***as a proxy*** for a selection on the basis of the specified difference in elongation at yield. The Examiner's assertions regarding inherency are therefore irrelevant to the claim.

For the additional reasons that the particular difference parameters specified in claims 44 and 45 cannot be derived from anything taught in Pepin et al the anticipation rejection of claims 44 and 45 should be reversed.

Respectfully submitted,

VIDAS, ARRETT & STEINKRAUS

Date: September 7, 2007

By: /Walter J. Steinkraus/
Walter J. Steinkraus
Registration No.: 29592

6640 Shady Oak Dr., Suite 400
Eden Prairie, MN 55344-7834
Telephone: (952) 563-3000
Facsimile: (952) 563-3001

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(viii) Claims appendix.

23. A method of making a parison for forming a medical device balloon in which portions of the parison are slated to form cone and waist portions of the balloon and a portion is slated to form the balloon body, the method comprising a step of extruding polymeric material to form a tube, and forming the parison having said slated portions from the tube, wherein the extruding step is controlled to provide the extruded tube with a varying longitudinal orientation, such that the slated parison formed therefrom has variation providing a lower or higher orientation for the cone and waist slated portions of the parison relative to the portion slated to form the balloon body.

24. A method as in claim 23 wherein the extruding step is controlled to provide the portion slated to form the body with a higher relative longitudinal orientation, the portions slated to form the waists of the balloon with a lower relative longitudinal orientation and the portions slated to form the cones of the balloon with a varying longitudinal orientation ranging between the higher and the lower relative orientations.

25. A method as in claim 23 wherein the extruding step is controlled to provide the extruded tube with a varying wall thickness, the variation providing a lower wall thickness for the cone and waist slated portions of the parison relative to the portion slated to form the balloon body.

43. A method of forming a polymeric tubing segment for a medical device comprising extruding a tube of polymeric material through a die and cooling the extruded tubing by drawing it through a cooling region spaced at a gap length from the die to the cooling bath, wherein the drawing rate, or the gap length, or the cooling rate of the cooling region, or any combination thereof, is altered along the length of the segment, whereby the segment is formed with at least two regions along the length thereof, a first of said regions and a second of said regions having

different elongation at yield properties relative to each other and wherein

said alteration of the drawing rate, or the gap length, or the cooling rate of the cooling region, or combination thereof, is selected on the basis of the elongation at yield properties of said first and second regions.

44. A method as in claim 43 wherein said alteration is selected to provide one of said regions with a elongation at yield which is at least 20% below the elongation at yield of another of said regions.

45. A method as in claim 43 wherein said alteration is selected to provide one of said regions with a elongation at yield which is 30% below the elongation at yield of another of said regions.

(ix) Evidence appendix.

None

(x) *Related proceedings appendix.*

None